



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,725	03/25/2004	Frank A. Chan	7404-602	8166

41577 7590 10/11/2006

WOODARD, EMHARDT, MORIARTY, MCNETT & HENRY LLP
111 MONUMENT CIRCLE, SUITE 3700
INDIANAPOLIS, IN 46204-5137

EXAMINER

TOWA, RENE T

ART UNIT	PAPER NUMBER
----------	--------------

3736

DATE MAILED: 10/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/809,725	CHAN, FRANK A.	
	Examiner	Art Unit	
	Rene Towa	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12-28 and 30-35 is/are pending in the application.
- 4a) Of the above claim(s) 36 and 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 5-10, 12-14, 17-28 and 30-31 is/are rejected.
- 7) ☒ Claim(s) 3, 4, 15, 16 and 32-35 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office action is responsive to an amendment filed July 24, 2006. Claims 1-10, 12- and 28-35 are pending. Claims 1, 4, 6, 12-13, 15, 20, 26 and 30 have been amended. New claims 32-37 have been added. Claims 11 and 29 have been cancelled.

Election/Restrictions

2. Newly submitted claims 36-37 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the different inventions have different designs and thus different modes of operation, and effects; for example the originally claimed invention discloses an expression member having a band 116 whereas newly submitted claims 36-37 discloses an expression member having a plurality of nubs.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 36-37 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Objections

3. Claims 32-33 are objected to because of the following informalities:

at lines 2-3, the limitations "the expression lobe" at lines 2, and "the compression lobe" at line 3 render the claim indefinite. From the alternative language in claim 3, it is unclear whether or not the claims a single or a plurality of lobes; the Examiner suggests

Art Unit: 3736

that the Applicant amend the claim to read --the at least one expression lobe-- at line 2 and --the at least compression lobe-- at line 3, respectively.

Further in regard to claim 32, at line 1, "The sample device" should apparently read --The sampling device-- to avoid a potential lack of antecedent basis.

Further in regard to claim 33, at line 4, "the lobes" should apparently read --the lobes--.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1-2, 5, 7, 10, 12-14, 17-22, 25-27 and 30-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Bajaj et al. (US Patent No. 6,056,765).

In regards to claim 1, Bajaj et al. discloses a sampling device, comprising:

a lancet 108 configured to form an incision in skin;

an expression member 100 having a band 116 positioned to contact skin that is deformable to squeeze skin around the incision;

wherein the band 116 is moveable between a relaxed position over the incision in skin and a contracted position over the incision;

a compression member (102, 104) configured to contact and traverse the expression member 100 wherein the band 116 compresses from the relaxed position to the contracted position to express bodily fluid from the incision in skin;

a housing configured to contact the skin near the incision; and

wherein at least a portion of the expression member 100 is resilient in order to return to the relaxed position.

In regards to claim 2, Bajaj et al. discloses a sampling device wherein the band 116 has an annular shape (see fig. 1).

In regards to claim 5, Bajaj et al. discloses a sampling device wherein the band 116 is resilient (see figs. 7-9).

In regards to claim 7, Bajaj et al. discloses a sampling device wherein the housing has a concave shape (see figs. 7-9).

In regards to claim 10, Bajaj et al. discloses a sampling device wherein the compression member (102, 104) includes a passageway 136a-b to at least partially receive the expression member 100 (see figs. 1 & 7-9).

In regards to claim 12, Bajaj et al. discloses a sampling device comprising:
an expression member 100 having a skin contacting portion that is moveable between a relaxed position over an incision in skin and a contracted position over an incision;

a compression member (102, 104) configured to contact the skin contacting portion of the expression member 100 to move the skin contacting portion from the relaxed position to the contracted position;

a housing to contact the skin near the incision; and

wherein at least a portion of the expression member 100 is resilient in order to return to the relaxed position (see figs. 7-9).

In regards to claim 13, Bajaj et al. discloses a sampling device wherein the expression member 100 includes a passageway that is moveable between a relaxed position over the incision in the skin and a contracted position over the incision (see figs. 7-9).

In regards to claim 14, Bajaj et al. discloses a sampling device wherein the passageway is resilient (see figs. 7-9).

In regards to claim 17, Bajaj et al. discloses a sampling device wherein the expression member 100 includes at least one resilient band 116 (see figs. 7-9).

In regards to claim 18, Bajaj et al. discloses a sampling device wherein the band 116 is configured to express bodily fluid from the incision (see figs. 7-9).

In regards to claim 19, Bajaj et al. discloses a sampling device wherein the band 116 has an annular shape (see figs. 7-9).

In regards to claim 20, Bajaj et al. discloses a sampling device wherein the expression element includes at least one resilient finger 116 (see figs. 7-9).

In regards to claim 21, Bajaj et al. discloses a sampling device wherein the finger 116 is configured to express bodily fluid from the incision (see figs. 7-9).

In regards to claim 22, Bajaj et al. discloses a sampling device further comprising a lancet 108 configured to form the incision in skin (see fig. 1).

In regards to claim 25, Bajaj et al. discloses a sampling device wherein the housing is a concave shape (see figs. 7-9).

In regards to claim 26, Bajaj et al. discloses a method of expressing a body fluid, comprising:

positioning a sampling device over an incision in skin; the sampling device having an expression member, a compression member, and a housing to contact the skin near the incision;

moving the expression member from a relaxed position to a contracted position to squeeze and compress the skin near the incision by rotating the compression member about the expression member; and

expressing body fluid from the incision with the sampling device by repeatedly squeezing and compressing the skin around the incision to allow body fluid to flow to the incision (see figs. 7-9).

In regards to claim 27, Bajaj et al. discloses a method of expressing a body fluid, further comprising: forming the incision in skin with a lancet 108 of the sampling device (see figs. 7-9).

In regards to claim 30, Bajaj et al. discloses a method of expressing a body fluid, wherein the expression member 100 moves from the contracted position to the relaxed position (see figs. 7-9).

In regards to claim 31, Bajaj et al. discloses a method of expressing a body fluid, wherein the housing is a concave shape to urge body fluid towards the incision in skin (see figs. 1 & 6).

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 8-9, 23-24 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bajaj et al. ('765) in view of Mitchen (US Patent No. 5,014,718).

Bajaj et al. disclose(s) a system, as described above, that teaches all the limitations of the claims except Bajaj et al. do not teach a test strip for collecting and testing the body fluid. However, Mitchen discloses a sampling device 1 comprising a test strip 19 for collecting and testing the body fluid (see figs. 2-4). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Bajaj et al. with a test strip similar to that of Mitchen in order to test the body fluid (see Mitchen, column 3/lines 12-16).

Allowable Subject Matter

8. Claims 3-4, 6, 15-16 and 32-35 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed July 24, 2006, with respect to the Searle et al. reference have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Bajaj et al. (see rejections supra).

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

Art Unit: 3736

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rene Towa whose telephone number is (571) 272-8758. The examiner can normally be reached on M-F, 8:00-16:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you

Art Unit: 3736

have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RTT


MARK LUNDENBURG
SENIOR PATENT EXAMINER
TECHNOLOGY CENTER 3700